ALLERGY RELIEF- diphenhydramine hcl tablet, film coated DOLGENCORP, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Rexall 44-329

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - itchy, watery eyes
 - itching of the nose or throat
 - sneezing
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- avoid alcoholic beverages

- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

adults and children 12 years and over	1 to 2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use

Other information

- each tablet contains: calcium 30 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package
- protect from moisture

Inactive ingredients

corn starch, D&C red #27 aluminum lake, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Principal Display Panel

Since 1903 Rexall®

Allergy Relief

Diphenhydramine HCl 25 mg Antihistamine

Relief of

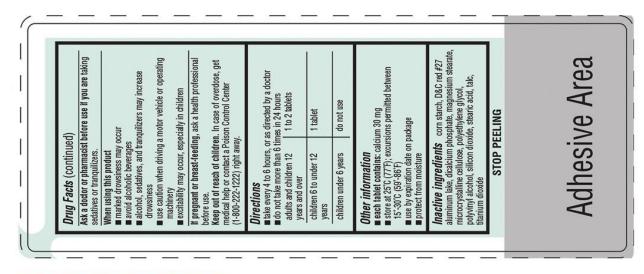
Sneezing

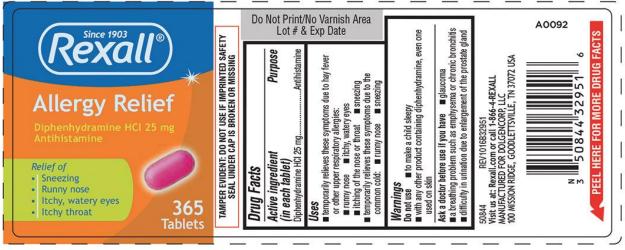
- Runny nose
- Itchy, watery eyes
- Itchy throat

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

50844 REV1016B32951

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Rexall 44-329

ALLERGY RELIEF

diphenhydramine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-329
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics				
Color	pink	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	44;329	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55910- 329-08	1 in 1 CARTON	03/02/1990	02/15/2021		
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:55910- 329-51	365 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/02/1990			

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date					
OTC monograph final	part341	03/02/1990			

Labeler - DOLGENCORP, LLC (068331990)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(55910-329)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(55910-329)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(55910-329), pack(55910-329)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(55910-329)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(55910-329)

Revised: 3/2021 DOLGENCORP, LLC